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<tr><th colspan="2">Louisiana Office of Public Health Laboratories</th></tr>
<tr><td>Test Name</td><td>Zika MAC-ELISA</td></tr>
<tr><td>PHL Location</td><td>Office of Public Health Laboratory Baton Rouge</td></tr>
<tr><td>CPT Code</td><td>86790</td></tr>
<tr><td>Synonyms</td><td>Zika</td></tr>
<tr><td>Brief Description of Test</td><td>Prior authorization required. Contact Infectious Disease Epidemiology at 800-256-2748.

IgM antibody capture enzyme-linked immunosorbent assay (MAC-ELISA) for the presumptive detection of antibodies to Zika virus in persons meeting Centers for Disease Control and Prevention (CDC) clinical and/or epidemiological criteria for Zika virus testing.

Please Note: Current guidance is to run Zika, Chikungunya and Dengue IgM together. While this guidance is in place, specimens that meet acceptance criteria for all three assays will have three separate results.</td></tr>
<tr><td>Possible Results</td><td>
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<tr><th>Test Specimen P/N</th><th>Interpretation</th><th>Report</th><th>Action</th></tr>
<tr><td>< 2</td><td>Negative</td><td>No evidence of recent Zika virus infection detected.</td><td>Report results.
If an early acute specimen, refer to interpretation instructions above.</td></tr>
<tr><td>2 ≤ P/N < 3</td><td>Equivocal</td><td>Zika MAC-ELISA results were equivocal for the presence of anti-Zika virus antibodies.</td><td>Send report to CDC along with the specimen for confirmatory testing.</td></tr>
<tr><td>≥ 3</td><td>Presumptive Positive</td><td>Serological evidence of possible recent Zika virus infection identified. Additional testing required.</td><td>Send report to CDC along with the specimen for confirmatory testing.</td></tr>
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<tr><td>Reference Range</td><td>Negative</td></tr>
<tr><td>Specimen Type</td><td>Serum or CSF. CSF may only be tested when submitted alongside a patient-matched serum specimen.</td></tr>
<tr><td>Specimen Container(s):</td><td>Red top tubes, Marble top tubes, polypropylene vials</td></tr>
<tr><td>Minimum volume accepted:</td><td>300 µL</td></tr>
<tr><td>Collection Instructions</td><td>Specimens should only be collected by personnel that have been properly trained. Care should be taken during specimen collection and handling to avoid generation of aerosols. Blood should be collected in a plastic tube, such as a vacutainer, which does not contain an anticoagulant. The collection tube may or may not contain a serum</td></tr>
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	separator. If collected in a tube without serum separator, serum must be aliquoted into screw cap tubes before shipment to laboratory. Depending on the type of collection tube, the amount of time it will take for the blood to clot could take up to 60 minutes. Separation of serum from cells should take place within 2 hours of collection to prevent erroneous test results according to NCCLS guidelines. Follow the package insert for the collection tube you use. Specimens other than serum should be collected in polypropylene vials. Label specimen with Patient Name and a 2nd unique identifier such as a chart number or medical record number. DOB is not considered unique. Complete a Lab Form 96 to accompany the sample(s). Each specimen must have a separate lab submission form. Lab submission forms must be thoroughly completed with patient's first and last name, 2nd patient identifier, gender, date of birth, date of collection, time of collection, onset date, test requested (ZIKA MAC-ELISA), and submitter's name, address, and contact number. Two unique identifiers **MUST** be recorded on the tube **AND** the Lab 96 form. A missing identifier on the tube will be an automatic rejection. If the identifiers are missing from the Lab 96 form, the submitter must be contacted and a new form with this information must be faxed back to the lab before testing will take place. Transport specimen to laboratory as soon as possible after collection. Keep submission forms insulated from specimens.
Storage and Transport Instructions	Once prior test authorization has been given by Infectious Disease Epidemiology, take a venous, whole blood sample. Follow serum specimen collection devices manufacturer instructions for proper collection, separation and storage methods. Store all diagnostic specimens at 2-8° C prior to testing. Avoid repeated freeze-thaw cycles.
Causes for Rejection	Unspun samples, tubes that contain less than 90% of the total drawing capacity (QNS), incorrect specimen type, or expired collection tubes must be rejected. Improper storage and improper transport temperature requirements are also reasons for rejection.
Limitations of the Procedure	This assay was approved via an Emergency Use Authorization.
Interfering Substances	N/A
References	Package Insert: CDC Zika MAC-ELISA Zika MAC-ELISA FDA Letter of Authorization – February 26, 2016
Additional Information	Fact Sheets for Providers can be located at: http://www.fda.gov/downloads/MedicalDevices/Safety/EmergencySituations/UCM488041.pdf

	Fact Sheets for Patients can be located at: http://www.fda.gov/downloads/MedicalDevices/Safety/EmergencySituations/UCM488042.pdf Fact Sheets for Pregnant Women can be located at: http://www.fda.gov/downloads/MedicalDevices/Safety/EmergencySituations/UCM488043.pdf
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